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[54] MINIMALLY INVASIVE VALVE ANNULUS SIZER

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[51] **Int. Cl.**[7] **A61B 5/103**

[52] **U.S. Cl.** **600/587**; 623/2; 606/148; 33/512

[58] **Field of Search** 600/587; 623/2; 606/148, 150; 33/511, 512

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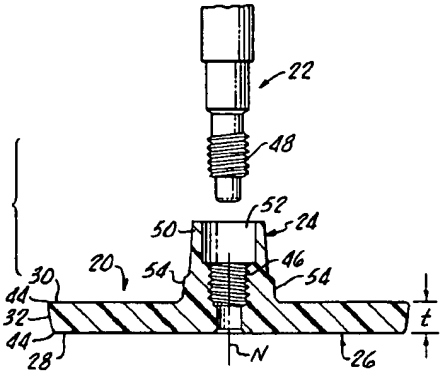
[57] **ABSTRACT**

An annulus sizer measures the size of a valve annulus during annuloplasty surgery. The annulus sizer includes a sizing portion for measuring the valve annulus and a coupling portion for attaching to a handle. The coupling portion is disposed on a proximal surface of the sizing portion. The sizing portion has a thickness on the order of about 0.1 inch. This relatively small thickness of the sizer facilitates minimally invasive annuloplasty surgery. For example, the sizer may be inserted through a relatively small intercostal incision. In addition, the relatively thin sizing portion minimizes optical distortion. The coupling portion may be disposed on the sizing portion at a location which is offset from the center of the sizer, thereby defining an enlarged viewing area. The coupling portion may have threading to engage with threading of the handle to ensure secure attachment.

39 Claims, 2 Drawing Sheets



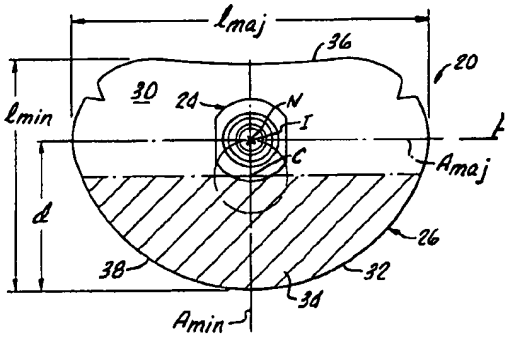


FIG. 1.
(PRIOR ART)

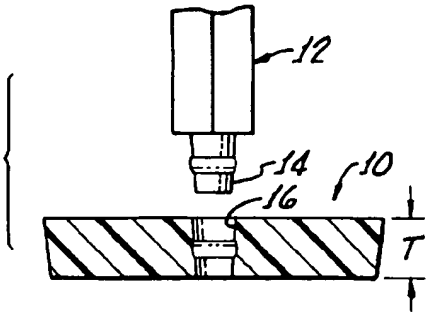
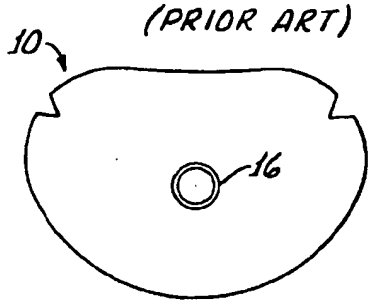


FIG. 2.
(PRIOR ART)



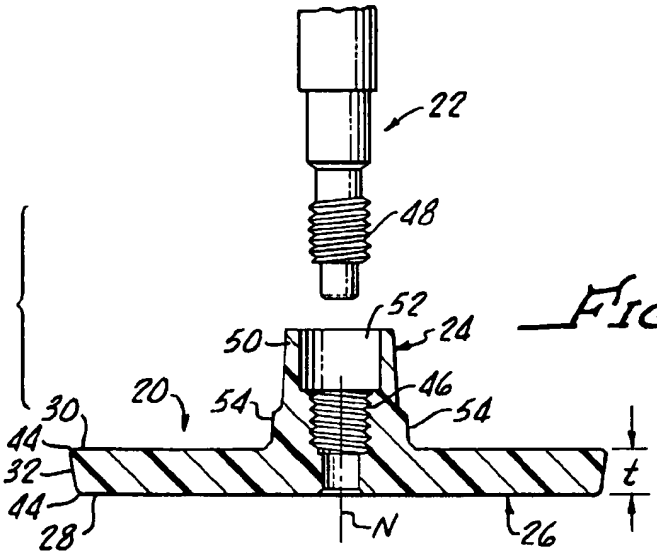


FIG. 3.

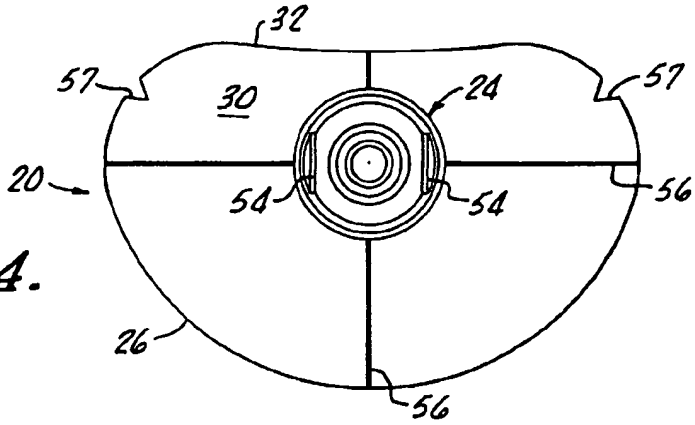


FIG. 4.

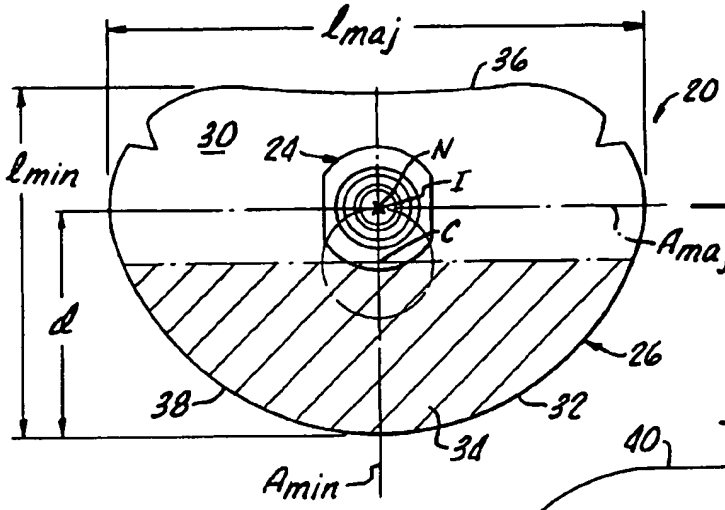


FIG. 5.

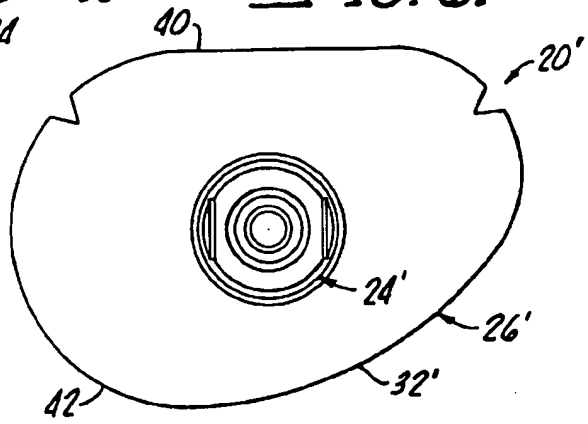


FIG. 6.

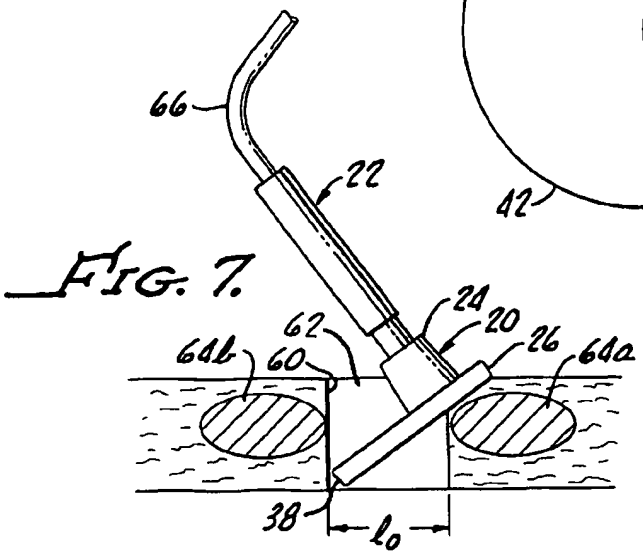


FIG. 7.

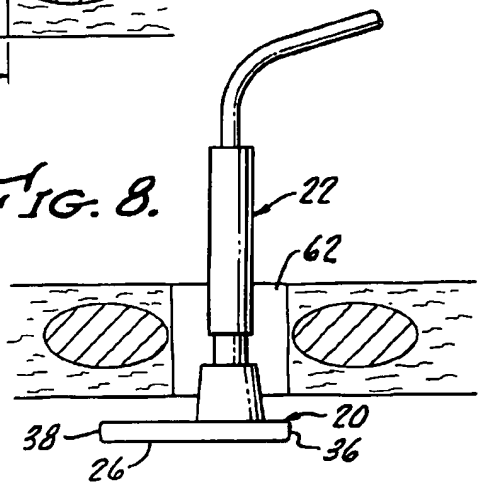


FIG. 8.

MINIMALLY INVASIVE VALVE ANNULUS SIZER

FIELD OF THE INVENTION

The present invention is directed to apparatus and associated methods for measuring the size of a heart valve annulus during annuloplasty surgery. Heart valve annuluses are measured in order to select a properly sized annuloplasty ring which is then implanted to repair a defective valve of the heart, such as the mitral valve or the tricuspid valve.

BACKGROUND OF THE INVENTION

The heart has four valves—two on the right (the pulmonary and tricuspid) and two on the left (the aortic and mitral)—that control the flow of blood through the chambers of the heart and out to the body. Although any of these valves may fail to function properly, disease most commonly affects the valves on the left side of the heart. The valves may narrow (called stenosis); the valves may not close all the way (causing a backflow of blood called regurgitation); or the valves may close incorrectly (called prolapse). A heart murmur represents the sound that a leaky or narrowed heart valve makes as blood moves through it.

The Aortic and Mitral Valves

Aortic stenosis is a narrowing of the aortic valve, through which blood flows from the left ventricle of the heart to the aorta, the major artery whose branches supply blood to various parts of the body. Sometimes this narrowness is a congenital (i.e., inborn) defect, but more often the valve narrows as a consequence of aging, or of infections, such as rheumatic fever. Aortic stenosis results in the left ventricle having to work harder and harder to push blood out. As this occurs, the muscular walls of the ventricle thicken, increasing their requirement for oxygen. Symptoms of aortic stenosis include chest pain when the oxygen needs exceed the supply from the coronary arteries; fainting (syncope), if the valve becomes very narrow; and congestive heart failure, which usually does not occur unless the valve has been narrowed for many years. Valve replacement, either with a mechanical valve made of metal or plastic or with a valve from a pig, may provide substantial relief from such valvular conditions.

In mitral stenosis, the valve opening between the upper and lower chambers on the left side of the heart has become narrowed. The cause is generally rheumatic fever, which is now rare in most developed countries but is common in many parts of the world, or results from other degenerative diseases and aging. When mitral stenosis occurs, the narrow valve impedes the entry of blood into the left ventricle from the atrium. Pressure builds up behind the valve, leading to an elevation of pressure in the lungs. This in turn may lead to shortness of breath (dyspnea), which is one of the major symptoms of mitral stenosis. Often, however, it occurs without any symptoms.

In aortic regurgitation, the aortic valve fails to close completely after the heart has pumped blood out into the aorta. Blood leaks back from the aorta into the left ventricle. In mitral regurgitation, improper closure causes blood to leak from the left ventricle back into the left atrium. In either case, the valve does not close properly because of a physical change in its shape or its support. This change may be the result of rheumatic fever; an infection (endocarditis), which may leave the valve scarred; or a heart attack, which causes loss of supporting muscle tissue. In the mitral valve, the change may be the result of a heart attack, which causes a loss of muscle tissue, or a spontaneous rupture of one of the muscular chords (chordea tendineae) that normally act as guide wires to keep the mitral valve in place.

Major symptoms of defective mitral valves include fatigue, shortness of breath, and edema. Medications such as digitalis, diuretics, and angiotensin-converting enzyme (ACE) inhibitors can help alleviate symptoms. Some defective mitral valves can be reconstructed or, failing that, replaced by an artificial valve.

The Pulmonary and Tricuspid Valves

In the pulmonary and tricuspid valves, any narrowing is rare and almost always congenital. Leakage, or regurgitation, is unusual, but may occur when use of illicit intravenous drugs leads to infection that damages the valve. The infection, hallmarked by fever, often settles on these two valves because they are the first ones bacteria come in contact with as they travel through the bloodstream. If the valve becomes leaky, swelling of the abdomen and legs may occur. As with other valves, treatment can include replacement, but this is rare and usually not as effective as it is when the aortic or mitral valve is involved.

Treatment

There are several treatments currently used to improve the performance of defective or diseased valves. Drugs such as digitalis medications, vasodilators, diuretics, anticoagulants, and antiarrhythmics may be administered for valve disorders. Rather than being curative, however, the major functions of these drugs are to reduce the severity of the symptoms, possibly reduce the workload of the heart, and prevent complications.

Balloon valvuloplasty may be used to correct narrowing of the mitral valve and occasionally the aortic valve by partially clearing obstructions. In use, a deflated balloon attached to the end of a catheter is introduced through an artery into the heart to the center of the valve opening and then inflated. The inflated balloon presses back the calcium in the valve or corrects the anatomical deformity that has caused the narrowing.

Alternatively, the diseased valve may be replaced with an artificial valve. Valve-replacement surgery is usually recommended when the damage to the valve is sever enough to be potentially life-threatening, as in the case of severe aortic stenosis. The mitral and aortic valves are the heart valves that most often need to be replaced. Artificial valves have been in use since 1952, when Charles Hufnagel successfully replaced a patient's aortic valve with a caged-ball valve.

Another method for treating defective valves is through reconstruction, which is typically used on minimally calcified valves. One type of reconstructive surgery is known as annuloplasty. An annuloplasty is performed to correct mitral valve insufficiency and/or stenosis. Annuloplasty involves implanting an annuloplasty ring on the valve annulus. The annuloplasty ring is designed to support the functional changes that occur during the cardiac cycle: maintaining coaptation and valve integrity in systole while permitting good hemodynamics in diastole.

To perform a successful annuloplasty, the size of the valve annulus where the annuloplasty ring is to be implanted must be accurately measured. Sizing is achieved by measuring the width and the height of the anterior leaflet with sizing obturators or, in the vernacular, valve sizers. Once the size has been determined, a proper annuloplasty ring may be selected and implanted.

A conventional annulus sizer currently used in annuloplasty surgery is illustrated in FIGS. **1** and **2** and is generally referenced with numeral **10**. The sizer **10** has a thickness T which is on the order of 0.28 inch and is made of a transparent polymer. The sizer **10** snaps onto a handle **12**

with male and female couplers **14** and **16**, respectively. The female coupler **16** is formed substantially in the centroid of the somewhat oval-shaped cross-section sizer **10**, as shown in FIG. **2**. In use, the surgeon estimates the valve annulus size and selects a sizer accordingly. The sizer is snapped onto the end of the handle and guided into proximity of the annulus, which may involve passing the sizer through a relatively small access channel, especially in minimally invasive surgical procedures. The final seating of the sizer in the annulus may necessitate viewing the annulus through the transparent sizer, though the polymer material is not a perfect transmitter of light. The sizer thickness serves to provide tactile feedback to the surgeon for a range of depths of the annulus. That is, the surgeon often pushes the sizer well into the annulus to engage the entire side wall of the sizer, which tends to average the overall resistance to in-and-out movement, and is desired by some surgeons. The central location of the handle connection also balances moments imposed on the sizer as transmitted to the handle. If the sizer is not quite the right size, it is withdrawn and detached from the handle, being replaced by a different sizer. In the insertion or withdrawal steps, the sizer may be accidentally pried off the handle because of the snap fit, though the same attribute of ease of detachment is viewed as a plus to enable rapid switching of different sizers. Additionally, with the trend toward smaller and smaller access channels, the size of devices such as sizers and valves is becoming a limiting factor.

Accordingly, in view of the foregoing, it is an object of the present invention to provide annulus sizers which eliminate many of the drawbacks associated with conventional sizers.

It is an additional object of the present invention to provide annulus sizers which enable a surgeon to clearly view a surgical field.

It is yet another object of the present invention to provide annulus sizers which facilitate annuloplasty procedures through rapid yet secure attachment to handles.

It is still another object of the present invention to provide methodology which enables surgeons to measure the size of valve annuluses in a minimally invasive manner.

SUMMARY OF THE INVENTION

These and other objects are achieved by the surgical apparatus and associated methods of the present invention which enable a surgeon to accurately measure the size of a valve annulus and then to properly select an annuloplasty ring during annuloplasty surgery.

According to one aspect of the invention, an annulus sizer includes a sizing portion with a coupling portion disposed on a proximal surface thereof. The sizing portion measures a valve annulus, and the coupling portion attaches to a handle. The sizing portion has a thickness on the order of about 0.1 inch. The relatively small thickness of the sizer facilitates minimally invasive annuloplasty surgery. For example, rather than accessing the heart through a sternotomy, a relatively small incision may be made intercostally through which the relatively thin sizer of the invention may be inserted. In addition, the relatively thin sizing portion minimizes optical distortion therethrough so that the surgeon is able to view the surgical field more clearly.

In accordance with another aspect of the invention, the coupling portion may be disposed on the sizing portion at a location which is offset from the center of the sizer. Accordingly, an enlarged viewing area is defined on the sizing portion. Augmenting the advantages of low optical distortion, the enlarged viewing area enhances the surgeon's view of the surgical field.

Another aspect of the invention involves securely attaching the sizer to a handle to prevent inadvertent detachment. This is accomplished by providing the coupling portion with threading to engage with threading of the handle. The threading preferably has a large pitch so that the sizer can be attached to the handle in just a couple of turns and in a secure and reliable manner. As time is of the essence during annuloplasty surgery, this secure yet quick attachment feature of the invention is particularly advantageous.

Other aspects, features, and advantages of the present invention will become apparent to those persons having ordinary skill in the art to which the present invention pertains from the following description taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a cross-sectional view of a conventional annulus sizer and handle end;

FIG. **2** is a plan view of the conventional annulus sizer;

FIG. **3** is a cross-sectional view of an exemplary annulus sizer and handle end for use during minimally invasive surgical procedures in accordance with the present invention, particularly illustrating a sizer for measuring a mitral valve annulus;

FIG. **4** is a plan view of the annulus sizer of the invention;

FIG. **5** is a plan view of the annulus sizer of the invention, particularly illustrating a preferred handle attachment location which enhances visibility during minimally invasive procedures;

FIG. **6** is a plan view of another exemplary annulus sizer of the present invention, particularly illustrating a sizer for measuring a tricuspid valve annulus;

FIG. **7** is a diagrammatic view of a surgical implement for measuring annuluses during a minimally invasive procedure with a patient shown in cross section, particularly illustrating a step of entering a chest cavity intercostally; and

FIG. **8** is a view similar to that of FIG. **7**, particularly illustrating a subsequent step in the minimally invasive annulus measuring procedure, particularly illustrating a sizer of the present invention within the chest cavity.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to the drawings in more detail, an exemplary embodiment of a valve sizer **20** of the present invention is illustrated in FIG. **3** in conjunction with a surgical handle **22**. Exemplary sizer **20** includes a coupling portion **24** and a sizing portion **26**. The coupling portion **24** includes structure for releasably attaching to the handle **22**, which will be discussed in more detail below. With additional reference to FIG. **4**, the sizing portion **26** is utilized to determine the size of a valve annulus during annuloplasty surgery. Exemplary sizer **20** is configured to measure the annulus of a mitral valve, which will be discussed in more detail below.

Exemplary sizing portion **26** is substantially flat and thin, with a distal surface **28**, a proximal surface **30**, and a thin peripheral side wall **32** extending between the surfaces. As shown, the coupling portion **24** is disposed on the proximal surface **30** of the sizing portion **26**, and may be integrally molded together therewith. The sizing portion **26** has a thickness t that is substantially less than the thickness of conventional sizers, as discussed below.

Exemplary sizer **20** is made from biocompatible material that is also preferably optically transparent and substantially

rigid. An exemplary material for the sizer **20** is polysulfone, or other similar thermoplastic. The thickness t of the sizing portion **26** is preferably minimized while still retaining substantial strength to prevent substantial flexing or bending or to prevent breakage. Generally speaking, the thickness t of the sizing portion **26** may be less than about 0.2 inch but is preferably on the order of about 0.1 inch. Depending upon the material from which exemplary sizing portion **26** is made, the thickness t may be substantially less than 0.1 inch. In a commercial embodiment of the sizer **20**, the thickness t is about 0.115 inch.

Relatively thick conventional sizers distort the field of view due to refraction of light through the thermoplastic. In addition, conventional sizers are too thick to be utilized in many minimally invasive procedures because of the minimal size of openings to access the heart. In contrast, the minimized thickness t of exemplary sizer **20** of the present invention not only minimizes optical distortion but also facilitates insertion through small surgical openings common in minimally invasive procedures, an example of which will be discussed below.

Referencing FIG. **5**, the sizing portion **26** of exemplary sizer **20** has a center C which may be defined as lying at the center of a line of symmetry dividing the substantially bean-shaped sizing portion **26**. The line of symmetry is vertical in FIG. **5** and coincides with a line denoting a minor axis A_{min}. As shown, the coupling portion **24** is preferably positioned on the sizing portion **26** at a location which is offset toward a concave edge of the sizing portion **26** from the center C. Accordingly, an enlarged viewing area is defined on the sizing portion **26**. The enlarged viewing area is referenced by numeral **34** and is graphically represented in the drawings by the shaded area of the sizing portion **26**. Those of skill in the art will recognize that the location of the coupling portion **24** with respect to the sizing portion **26** may be generalized as offset away from a centroid, leaving a larger viewing area, such as indicated at **34**. In other words, though common, the particular bean shape of the present sizing portion **26** is exemplary only, and other sizer shapes are known.

As discussed above, conventional sizers have a socket for attaching to a handle disposed substantially at the center of the sizer. This limits a viewing area around the socket to a relatively narrow and concentric ring. In contrast to conventional sizers, exemplary sizer **20** of the present invention greatly increases the percentage of the field of view which a surgeon may see. Accordingly, the enlarged viewing area **34**, coupled with the minimal thickness t of the sizing portion **26** which minimizes optical distortion, enhances the ability of a surgeon to position the sizer in a valve annulus and to determine its size accurately.

Although exemplary sizer **20** may be configured in any desired manner, it is preferable for the sizing portion **26** to have a shape which is analogous to the shape of a healthy valve annulus and/or the shape of an annuloplasty ring. Accordingly, the sizing portion **26** may be noncircular in shape. More specifically, the sizing portion **26** for mitral valve annuluses is typically shaped somewhat like a kidney bean and, as shown in FIG. **5**, defines a major axis A_{maj} and the aforementioned minor axis A_{min}, which axes have an intersection I. The major axis A_{maj} is defined generally along the greater of the two dimensions of the sizer **20** (i.e., the horizontal dimension from apogee to apogee), and the minor axis A_{min} is defined generally along the lesser of the two dimensions of the sizer **20** (i.e., the vertical dimension). Again, the kidney-shaped mitral-valve sizer **20** shown in FIG. **5** is substantially symmetrical about the minor axis A_{min}.

Given the major and minor axes A_{maj} and A_{min} defined on exemplary sizer **20** of the invention, the coupling portion **24** may be positioned on the sizing portion **26** substantially at or near the intersection I. In other words, the coupling portion **24** may have an axis N defined therethrough (see FIG. **3**) which passes substantially through the intersection I of the axes A_{maj} and A_{min}.

With continued reference to FIG. **5**, as mentioned above, the coupling portion **24** may be offset from the center C. In this regard, the coupling portion **24** is preferably offset from the center C along the minor axis A_{min} and positioned substantially on the major axis A_{maj}. Depending upon the preferred embodiment of the sizer **20**, the location at which the coupling portion **24** is disposed on the sizing portion **26** may be further offset from the center C along the minor axis A_{min} toward the side wall **32**. Alternatively, the coupling portion **24** may be offset from the center C in any direction (indiscriminate of the axis A_{maj} and A_{min}) to define an enlarged viewing area on the sizing portion **26**.

Depending upon the configuration of the sizing portion **26**, the side wall **32** may have a plurality of different portions or segments defined therealong and separated by transitions in shape. For example, in the kidney-shaped configuration of the sizing portion **26** illustrated in FIG. **5**, the side wall **32** may have a concave side **36** and a convex side **38**. Although illustrated as a subtle curvature, the concave side **36** of the side wall **32** curves inwardly toward the center C at or near the minor axis A_{min}. Conversely, the convex side **38** of the side wall **32** curves outwardly from the center C at or near the minor axis A_{min}. Further to the description provided above, the coupling portion **24** may be positioned on the sizing portion **26** at a location which is closer to the concave side **36** than to the convex side **38** of the side wall **32**.

To further define the exemplary configuration of sizer **20** illustrated in FIG. **5**, the sizing portion **26** has a length l_{maj} defined along the major axis A_{maj} and a length l_{min} defined along the minor axis A_{min}, with the major-axis length l_{maj} being greater than the minor-axis length l_{min}. The relationship between the respective magnitudes the major- and minor-axis lengths $_{maj}$ and l_{min} is preferably defined as a ratio of about 3:2 to about 4:3. More desirably, and stated a different way, the major-axis length l_{maj} is about 1.2 to about 1.5 times greater than the minor-axis length l_{min}. Exemplary sizer **20** may be configured in accordance with other ratios of the lengths l_{maj} and l_{min} for use in specific valve-sizing applications. The major-axis length l_{maj} corresponds to and is used to measure the width of the anterior leaflet of a valve, and the minor-axis length l_{min}, corresponds to and is used to measure the height of the anterior leaflet.

In addition to lengths l_{maj} and l_{min}, a distance d, which is defined as the distance the major axis A_{maj} is from an apogee of the convex side **38** (i.e., the point at or near the intersection of the minor axis A_{min} and the convex side **38**), may be used to further define the configuration of the sizing portion **26**. The magnitude of the apogee distance d is greater than 50% of the minor-axis length l_{min} and is preferably greater than at least 60% to 70% of the minor-axis length l_{min}. In a preferred embodiment of a sizer **20** for measuring mitral-valve annuluses, the apogee distance d is about 65% of the minor-axis length l_{min}.

To measure the size of a valve annulus accurately, a plurality of sizers **20** of different dimensions is made available to a surgeon during an annuloplasty surgery, with each of the sizers corresponding to the size of an annuloplasty ring. As known in the art, annulus sizers are numbered according to the major-axis length l_{maj} in millimeters. The

numbering system for mitral-annulus sizers, for example, includes **24, 26, 28 . . . 40**. In accordance with a commercial embodiment of the present invention, a No. 36 sizer, for example, may have a major-axis length l_{maj} of about 1.5 inches, a minor-axis length l_{min} of about 1.0 inch, and an apogee distance d of about 0.65 inch.

Contrasting the substantially symmetrical configuration of the sizing portion **26** of exemplary sizer **20** for use in measuring a mitral valve annulus illustrated in FIG. **5**, the sizing portion may be configured substantially asymmetrically as shown in FIG. **6**, which illustrates an exemplary embodiment of a valve annulus sizer of the invention for use in measuring a tricuspid valve annulus. Exemplary tricuspid sizer shown in FIG. **6** is indicated with numeral **20** with the addition of a prime ('). The sizing portion **26'** of exemplary tricuspid sizer **20'** includes a substantially linear side **40** and an irregular convex side **42**. The irregularly shaped convex side **42** provides an enlarged viewing area on the sizing portion **26'**. The coupling portion **24'** is also shown in FIG. **6**.

Further referencing FIG. **3**, the side wall **32** may taper from the distal surface **28** to the proximal surface **30**. The tapered side wall **32** preferably angles outwardly so that the proximal surface **30** is larger than the distal surface **28**. The edges **44** defined between the side wall **32** and each of the surfaces **28** and **30** is preferably rounded to be substantially atraumatic.

With continued reference to FIG. **3**, the coupling portion **24** may be configured to be releasably attachable to the handle **22**. For example, the coupling portion **24** may include a threaded socket **46** for engaging with threading **48** disposed on a distal end of the handle **22**. The threading **46** and **48** preferably has a pitch which allows the sizer **20** to engage securely with the handle **22** in relatively few turns, for example, two or three turns. For example, the threading **46** and **48** may have a pitch of about 20 to 25 turns per inch. To facilitate a secure engagement, the coupling portion **24** preferably extends outwardly away from the proximal surface **30** of the sizing portion **26**, thereby defining a tubular boss **50**.

As shown in FIGS. **3** and **4**, a central channel **52** (with axis N) may extend through the coupling portion **24**, as well as through the sizing portion **26**. The coupling portion **24** may further include a pair of diametrically opposed planar surfaces **54**, which are clearly shown in FIG. **4**. Surfaces **54** may be used for grasping the sizer **20** with a tool other than the handle **22**, for example, with a forceps. As shown in FIG. **4**, the sizing portion **26** desirably includes cross hairs **56** formed on the proximal surface **30** to aid in making vertical and horizontal measurements in a valve annulus. In addition, the sizing portion **26** may include a pair of notches **57** corresponding to the commissures of a valve annulus for purposes of locating and orienting the sizing portion **26** in the valve annulus.

Although it may be used in any type of annuloplasty surgery, exemplary sizer **20** of the present invention is particularly useful in minimally invasive procedures. In annuloplasty surgery, a plurality of annuloplasty rings, each of a different size as known in the art, are provided. A plurality of sizers **20** are also made available to the surgeon. Each of the sizers **20** has a size corresponding to one of the annuloplasty rings.

Referencing FIGS. **7** and **8**, the heart of the patient is then accessed, which may be carried out through any type of conventional sternotomy or through a mini-thoracotomy. Access to the chest cavity is preferably accomplished in a minimally invasive manner, for example, through an intercostal incision **60** which defines an opening **62** between adjacent ribs **64*a*** and **64*b***. If desired, a retractor or a trocar (not shown) may be employed to maintain patency of the opening **62**. In addition, cartilage may be removed in forming the opening **62**, if desired and as known in the art.

The surgeon may then access the heart and the valve annulus of the defective valve. As mentioned above, the valve annulus needs to be measured to select a properly sized annuloplasty ring. To measure the annulus, one of the sizers is selected and positioned in the annulus. If the surgeon determines that this is not a proper sizer, another differently sized sizer may be selected and positioned in the annulus. This process, which is discussed in detail below, may be repeated until the surgeon determines the size of the annulus.

To carry out this procedure, one of the plurality of sizers **20** is selected and attached to the handle **22** as described above. The handle **22** is preferably made from a malleable material so that a bend **66** may be formed in the handle **22** to facilitate the procedure. To minimize trauma to the patient, the size of the opening **62** is preferably minimized. In this regard, the opening **62** preferably has a length l_o which is less than the minor-axis width l_{min} of the sizing portion **26**; for example, length l_o may be less than about an inch or, more preferably, less than about three-quarters of an inch.

In order to insert the sizer **20** through an opening **62** with a length l_o which is less than the minor-axis length l_{min} of the sizing portion **26**, the sizer **20** may be tilted obliquely to the opening **62** and then inserted through the opening **62**, with the convex side **38** defining a leading edge. When the convex side **38** has passed through the opening **62**, the sizer **20** may be tilted in a reverse manner while urging the concave portion **36** (which defines a trailing edge) through the opening **62**. When through, the sizer **20** may be positioned on or above the valve annulus to determine its size. The enlarged viewing area **34** enhances the surgeon's ability to view the surgical field with or without visual aids. The sizer **20** may be removed from the patient by essentially reversing the foregoing insertion procedure.

The minimized thickness t of the sizing portion **26** facilitates the insertion and the removal of the sizer **20** through the relatively narrow opening **62**. In addition, as the surgeon's field of view is limited by the size of the opening **62**, he or she may look through the transparent sizing portion **26** with minimal distortion. The threaded connection between the coupling portion **26** and the handle **22** ensures a secure attachment, which is beneficial in tight minimally invasive working environments. For example, pressure may be applied on the sizer **20** while being removed through the opening **62**, which pressure could possibly disengage conventionally attached sizers. In addition, the large pitch of the threading **46** and **48** allows the surgeon to quickly remove and reattach different sizers in a secure and reliable manner.

Those skilled in the art will understand that the embodiments of the present invention described above exemplify the principles of the invention and do not limit the scope of the invention to those embodiments of the surgical apparatus specifically illustrated in the drawings and described above. The exemplary embodiments provide a foundation from which numerous alternatives and modifications may be made, which alternatives and modifications are also within the scope of the present invention as defined in the appended claims.

What is claimed is:

1. A sizer for measuring a valve annulus, said sizer comprising:

a coupling portion for releasably attaching to a handle; and

a sizing portion for measuring a valve annulus;

said coupling portion being disposed on said sizing portion; and

said sizing portion having a thickness of less than about 0.2 inch.

2. A sizer as claimed in claim 1 wherein said sizing portion is optically transparent.

3. A sizer as claimed in claim 1 wherein said sizing portion has a major axis and a minor axis;

said sizing portion having a length along said major axis at least about 1.2 times greater than a length along said minor axis.

4. A sizer as claimed in claim 3 wherein said sizing portion has a major axis and a minor axis with an intersection;

said coupling portion being positioned substantially at said intersection.

5. A sizer as claimed in claim 1 wherein said sizing portion is substantially flat and thin, with a distal surface, a proximal surface, and a thin peripheral side wall.

6. A sizer as claimed in claim 5 wherein said proximal surface having a center, and said coupling portion is positioned on said sizing portion at a location which is offset from said center.

7. A sizer as claimed in claim 6 wherein said sizing portion has a major axis and a minor axis;

said coupling portion being offset from said center along said minor axis.

8. A sizer as claimed in claim 7 wherein said coupling portion is positioned substantially on said major axis.

9. A sizer as claimed in claim 1 wherein said sizing portion has a distal surface, a proximal surface, and a side wall;

said surfaces being substantially kidney shaped such that said side wall has a concave side and a convex side.

10. A sizer as claimed in claim 9 wherein said coupling portion is positioned on said sizing portion at a location which is closer to said concave side than to said convex side of said side wall.

11. A sizer as claimed in claim 9 wherein said sizing portion has a major axis and a minor axis;

said concave side being offset from said minor axis.

12. A sizer as claimed in claim 1 wherein said sizing portion has a distal surface, a proximal surface, and a side wall;

said side wall tapering from said distal surface to said proximal surface.

13. A sizer as claimed in claim 1 wherein said sizing portion has a distal surface, a proximal surface, and a side wall defining an edge with each of said surfaces;

said edges being rounded.

14. A sizer as claimed in claim 1 wherein said coupling portion includes threading.

15. A sizer as claimed in claim 1 wherein:

said sizing portion has a major axis and a minor axis with an intersection; and

said coupling portion has a central axis;

said coupling portion being positioned on said sizing portion such that said central axis substantially intersects said intersection.

16. A sizer for measuring a valve annulus, said sizer comprising:

a sizing portion for measuring a valve annulus and having a distal surface, a proximal surface, and a side wall having a thickness which is less than about 0.2 inch, the side wall defining a shape having a major axis and a minor axis, and a geometric center defined at the intersection of the major and minor axes; and

a coupling portion for releasably attaching to a handle and disposed on said sizing portion at a location which is generally on the minor axis and spaced from the nearest side wall a distance which is less than or equal to 40% of the minor axis.

17. Surgical apparatus for measuring a valve annulus, said surgical apparatus comprising:

a handle; and

a sizer including a coupling portion for attaching to said handle and a sizing portion for measuring a valve annulus;

said coupling portion being disposed on said sizing portion; and

said sizing portion having a thickness of less than about 0.2 inch.

18. Surgical apparatus as claimed in claim 17, wherein said coupling portion is releasably attachable to said handle.

19. Surgical apparatus as claimed in claim 18, wherein said coupling portion includes threading.

20. Surgical apparatus as claimed in claim 18, further comprising a plurality of said sizers;

each of said sizers having a sizing portion of predetermined size.

21. Surgical apparatus as claimed in claim 17, wherein said handle is bendable.

22. A method for measuring a valve annulus of a heart, said method comprising the steps of:

providing a handle;

providing a plurality of sizers, each of said sizers including a sizing portion having a thickness which is less than about 0.2 inch and a coupling portion disposed on a proximal side of said sizing portion;

selecting one of said sizers;

attaching said handle to said coupling portion of said selected sizer; and

positioning said attached sizer on a valve annulus having a size.

23. A method as claimed in claim 22, further comprising the steps of:

removing said selected sizer from the valve annulus;

detaching said handle;

selecting another one of said sizers;

attaching said handle to said coupling portion of said selected sizer; and

positioning said attached sizer on the valve annulus.

24. A method as claimed in claim 23, further comprising the step of:

repeating said further steps of claim 23 until the size of the valve annulus is determined.

25. A method as claimed in claim 22, further comprising the steps of:

providing a plurality of annuloplasty rings each of different size; and

selecting one of said annuloplasty rings which has a size corresponding to that of the valve annulus.

26. A method as claimed in claim 25, further comprising the step of:

implanting said selected annuloplasty ring on the valve annulus.

27. A method as claimed in claim 22, wherein said positioning step comprises the step of:

positioning said attached sizer on a valve annulus of a mitral valve.

28. A method as claimed in claim 27, wherein said positioning step comprises the step of:

positioning said attached sizer on a valve annulus of a tricuspid valve.

29. A method as claimed in claim 22, further comprising the step of:

providing access to the heart.

30. A method as claimed in claim 29, wherein said step of providing access comprises the step of:

providing access to the heart intercostally.

31. A method as claimed in claim 30, wherein said step of providing access comprises the step of:

forming an opening between two adjacent ribs.

32. A method as claimed in claim 31, further comprising the step of:

inserting said selected sizer through said opening.

33. A method as claimed in claim 22, wherein said step of providing a plurality of sizers comprises the step of:

providing a plurality of sizers each of which includes a sizing portion having a length defined along a major axis greater than a length defined along a minor axis.

34. A method as claimed in claim 33, further comprising the steps of:

forming an opening between two adjacent ribs such that said opening has an intercostal length less than said length defined along said minor axis of said sizing portion.

35. A method as claimed in claim 34, further comprising the steps of:

tilting said selected sizer such that said selected sizer is oblique to said opening; and

inserting said selected sizer through said opening.

36. A method as claimed in claim 35, wherein said inserting step comprises the step of:

inserting said selected sizer through said opening such that a leading edge of said sizer defined by said minor axis passes through said opening first.

37. A method as claimed in claim 35, wherein said step of providing a handle comprises the step of:

providing a handle which is bendable.

38. A method as claimed in claim 37, further comprising the step of:

bending said handle to facilitate said step of inserting said selected sizer.

39. A method as claimed in claim 22, wherein:

said step of providing a handle comprises the step of:

providing a handle with threading disposed on a distal end thereof;

said step of providing a plurality of sizers comprises the step of:

providing a plurality of sizers each of which includes a coupling portion with threading; and

said attaching step comprises the step of:

threading said selected sizer to said handle.

* * * * *

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United States Patent [19]

Kadhiresan

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[45] Date of Patent: Aug. 10, 1999

[54] **LONG TERM MONITORING OF ACCELERATION SIGNALS FOR OPTIMIZATION OF PACING THERAPY**

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[73] Assignee: **Cardiac Pacemakers, Inc.**, St. Paul, Minn.

[21] Appl. No.: **09/009,424**

[22] Filed: **Jan. 20, 1998**

[51] **Int. Cl.**[6] **A61B 5/0402**

[52] **U.S. Cl.** **600/513**; 600/514

[58] **Field of Search** 600/509, 513, 600/514

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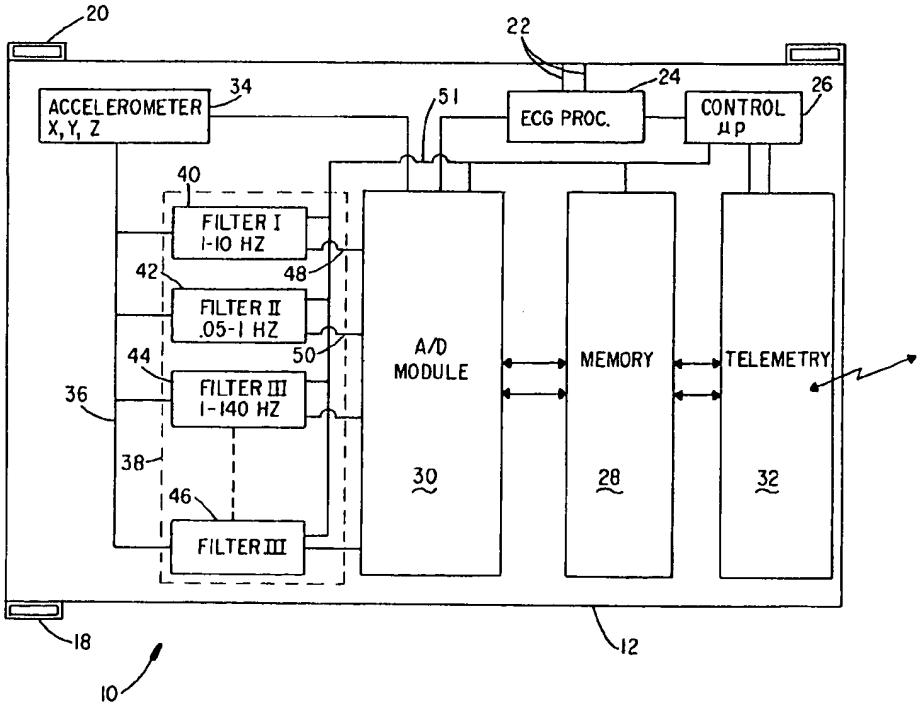
Attorney, Agent, or Firm—Haugen and Nikolai, P.A.

[57] **ABSTRACT**

An implantable monitor for collecting and storing for later telemetric readout physiologic data relating to cardiopulmonary performance. The monitor device includes an accelerometer and associated signal processing circuitry for analyzing the accelerometer output signal and deriving therefrom activity, respiratory, pulse pressure and heart sound information helpful in assessing the efficacy of therapy being rendered to the patient.

11 Claims, 3 Drawing Sheets



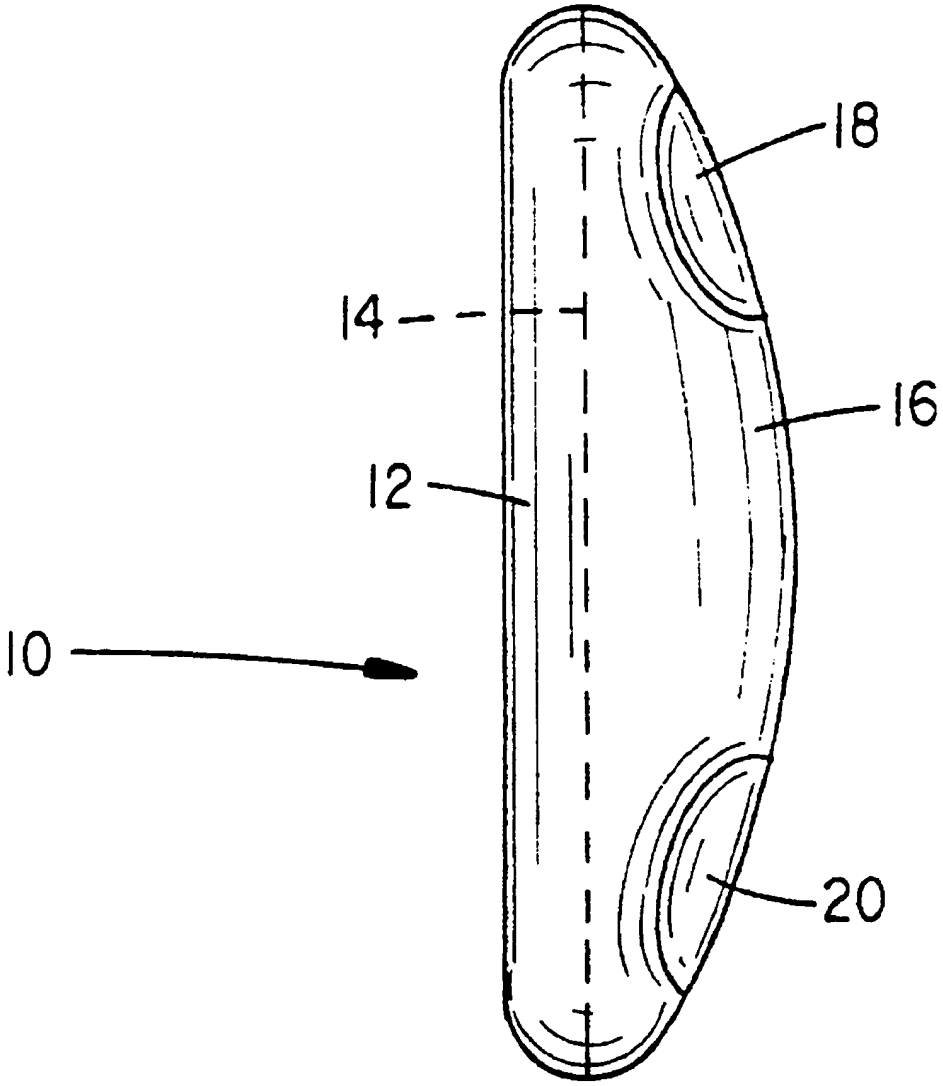


FIG. 1

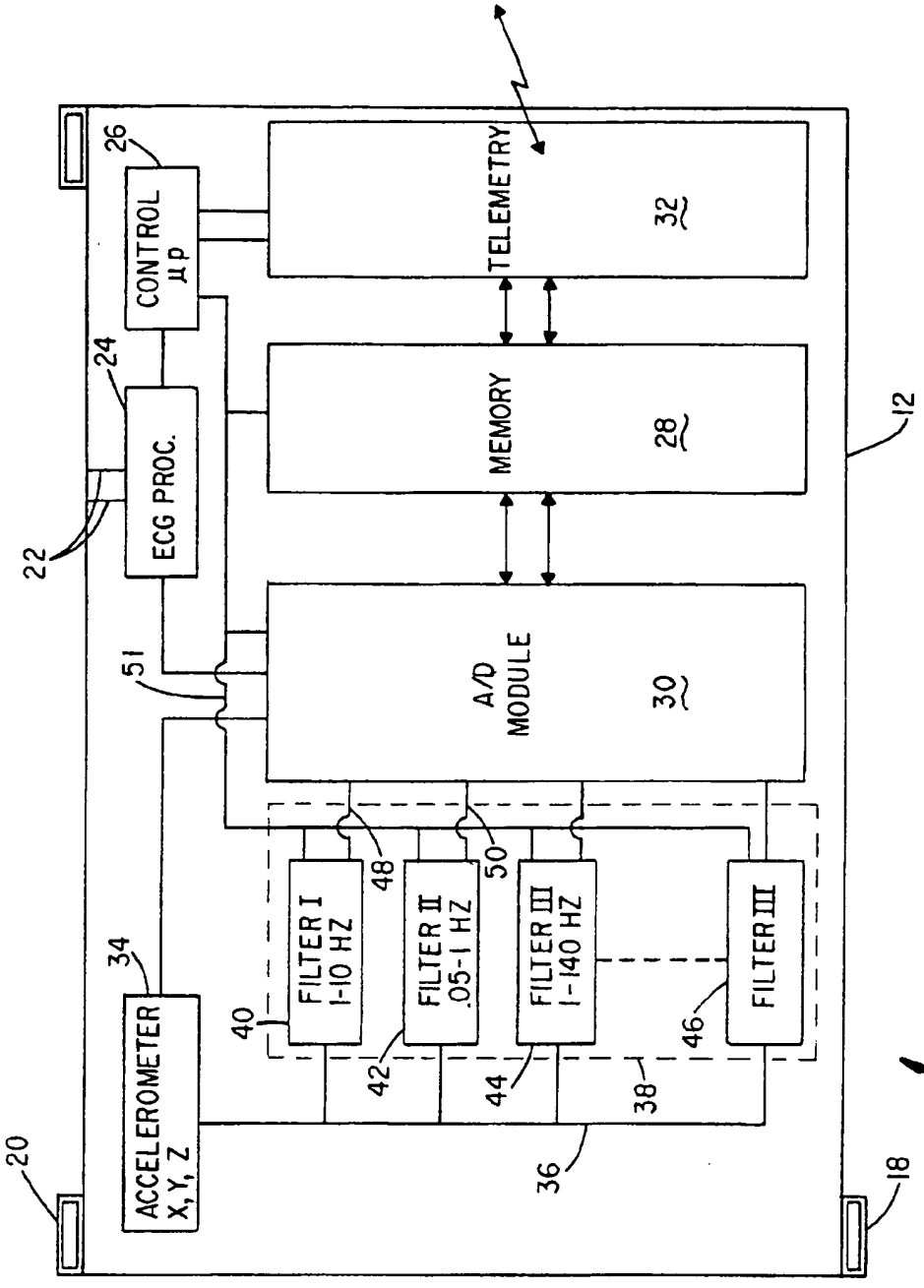

TELEMETRY
32
MEMORY
28
A/D MODULE
30
CONTROL μp
26
ECG PROC.
24
22
51
FILTER I 1-10 HZ
FILTER II .05-1 HZ
FILTER III 1-140 HZ
FILTER III
48
50
40
42
44
46
38
36
ACCELEROMETER X, Y, Z
34
20
18
12
10

FIG. 2

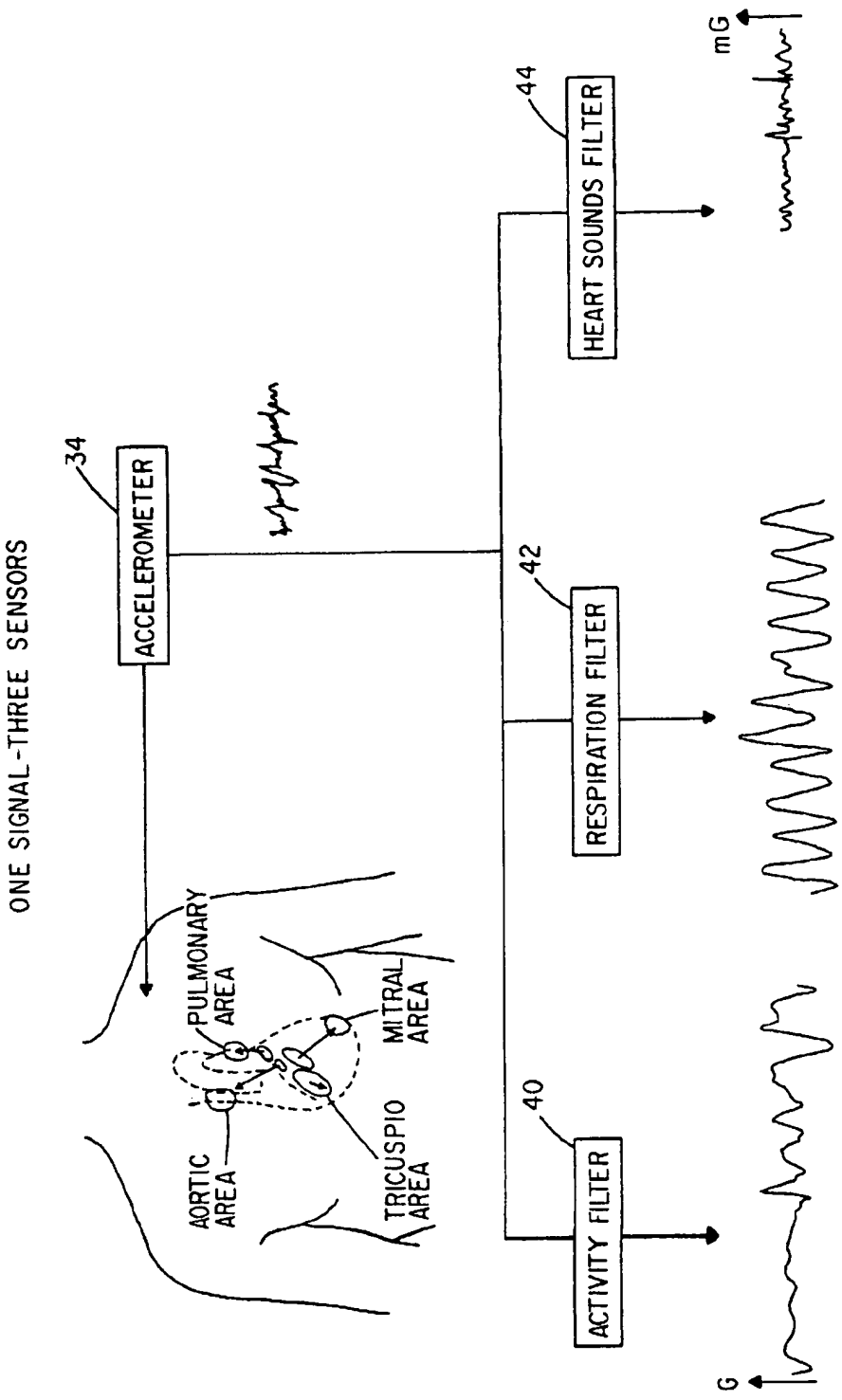

ONE SIGNAL-THREE SENSORS
34
ACCELEROMETER
PULMONARY AREA
MITRAL AREA
AORTIC AREA
TRICUSPIO AREA
40
ACTIVITY FILTER
42
RESPIRATION FILTER
44
HEART SOUNDS FILTER
G
mG

FIG. 3

LONG TERM MONITORING OF ACCELERATION SIGNALS FOR OPTIMIZATION OF PACING THERAPY

BACKGROUND OF THE INVENTION

I. Field of the Invention

This invention relates generally to apparatus for long-term monitoring of the physiologic condition of a patient, and more particularly to an implantable or external device incorporating a microprocessor, a memory and an accelerometer for detecting motion due to patient activity as well as motion components relating to respiratory and cardiac rhythms, and from which critical hemodynamic diagnostic information can be derived.

II. Discussion of the Prior Art

In long term treatment of patients having cardiac abnormalities, it is important to monitor the cardiac performance over prolonged periods to assess the efficacy of any pacing or drug therapy being rendered to that patient. While so-called Holter monitors can be used to record ECG waveforms for later playback and evaluation, the amount of information that can be obtained from the ECG waveforms is necessarily limited.

It is known that data relating to the heart's mechanical functioning as a pump can be derived from heart sounds. Variability in heart sounds can provide insight into a patient's hemodynamic status. Arterial pulse pressure and various other parameters such as pre-ejection period that can be used by a physician in programming a dual chamber pacemaker for optimizing its AV delay parameter for a given patient may also be obtained from heart sounds. The timing to second heart sound may also be used to govern the rate response called for by an activity based rate responsive pacemaker. Also, heart sounds can be used to detect the occurrence of systolic and diastolic murmurs associated with valvular insufficiency or regurgitation. For example, a loud late mitral component of heart sound S_1 is the hallmark of hemodynamically significant mitral stenosis. When S_1 is loud, it is always associated with a loud opening snap, and the intensity of the snap correlates best with valve mobility. When calcification of the mitral valve occurs, the valve is stenosed and hence S_1 is soft, and the opening snap is absent. In addition, high frequency heart sounds detected during diastole may contain information on occluded coronary arteries. See "Accelerometer Type Cardiac Transducer for Detection of Low-Level Heart Sounds" by Padmanabhan et al., *IEE Trans Biomed Eng.*, 1993 Jan.; 40(1):21–28. It is also known that monitoring respiratory function in heart failure patients can identify patients with abnormal breathing patterns such as Cheyne-Stokes. The frequency of sleep apneas can be documented as well.

The use of movement registration for daily physical activity assessment is important to determine patient status. Standard laboratory-based exercise tests often used to define prognosis in patients with chronic heart failure do not relate to measures of normal daily activity. See Walsh JT et al., "Relation of Daily Activity Levels in Patients With Chronic Heart Failure to Long-Term Prognosis", *Am J. Cardiol,* 1997 May 15;79(10):1364–1369.

Thus, a need exists for a monitor that not only gathers and stores data over extended periods relating to the heart's electrical performance, but also its mechanical performance. In addition, there is also a need to monitor a patient's respiratory function and activity profile. It is a principal object of this invention to meet these needs.

SUMMARY OF THE INVENTION

The present invention comprises a monitor for obtaining and storing physiologic information and, in the case of an implantable monitor, comprises a moisture impervious, biocompatible housing having a plurality of ECG electrodes on an exterior surface thereof adapted to contact dermal tissue of a patient in whom the monitor is implanted. Also contained within the housing is an accelerometer for detecting mechanical vibration of the housing due to physical activity of the patient and due to heart sounds and respiratory activity. The accelerometer responds to such motions by producing an electrical signal proportional thereto.

Also incorporated into the housing is signal processing circuitry (filters) coupled to receive the electrical signals from the accelerometer and from the ECG electrodes for isolating components of the electrical signal due to physical activity, respiratory activity and heart sounds. The output of the signal processing means may be applied to an A/D converter under control of a microprocessor for converting the ECG signals and the signal components processed from the accelerometer output to digital data. Associated with the microprocessor contained within the biocompatible housing is a memory for storing the digital data at addressable locations, which data may be subsequently read out from the implanted unit to an external device via a telemetry link. Being a microprocessor-based system, it can be programmed to initiate data collection at the onset of a predefined event, either in the ECG signal, e.g., a tachyrhythmia, or in the outputs of the filters, e.g., times of high or low activity.

DESCRIPTION OF THE DRAWINGS

The foregoing features, objects and advantages of the invention will become apparent to those skilled in the art from the following detailed description of a preferred embodiment, especially when considered in conjunction with the accompanying drawings in which:

FIG. **1** is a perspective view of an implantable monitor in accordance with the present invention;

FIG. **2** is a block diagram representation of an implantable sensor monitor of the present invention; and

FIG. **3** illustrates the accelerometer output signal and the signal components extracted therefrom proportional to activity, respiration and systolic and diastolic heart sounds.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to FIG. **1**, there is indicated generally by numeral **10** an implantable monitor device. It includes a moisture impervious, body implantable housing **12** containing within its hollow interior a battery power supply (not shown) and electronic circuitry, which will be more particularly described. The housing **12** is preferably fabricated in two halves from thin, light-weight titanium which are then welded together along a parting line **14**. The metallic housing **12** may be covered over its entire surface by a suitable insulator, such as a silastic coating **16**. Bonded to the coating layer **16** so as to be insulated from the housing **12** are a plurality of electrodes, as at **18** and **20**. The monitor module **10** may be surgically implanted in various locations to optimize signal-to-noise ratios. For example, to enhance mitral heart sounds, the device will ideally be implanted near the apex of the left ventricle or in the superior portion of the abdomen. To obtain better resolution of aortic heart sounds, the device may be implanted in the left or right pectoral area. It is preferably provided with a rounded contour so as not to create a noticeable bulge or cause necrosis when implanted beneath the patient's skin. The electrodes **18** and **20**, thus contact subdural tissue.

FIG. **2** is a block diagram representation of the electronic circuitry contained within the housing **12**. In FIG. **2** the housing is represented as a closed rectangle and with electrodes **18** and **20** disposed thereon. Wire feedthroughs as at **22** enter the housing through appropriate glass-to-metal seals to connect the electrodes **18** and **20** to a ECG processing module **24**.

A microprocessor-based controller **26** controls the operation of the monitor device **10** and has associated with it a memory **28** in which may be stored a program of instructions executable by the microprocessor in the controller **26**. The memory is also adapted to store digital information coming to it from an analog-to-digital converter module **30**.

Also included within the housing **12** is a conventional telemetry link **32** that is operatively coupled to the memory **28** whereby digital information stored therein may be transmitted to a remote (external) programmer and monitor device (not shown). The telemetry device **32** is standard and is of the type commonly found in implantable cardiac rhythm management devices, such as pacemakers and defibrillators.

An accelerometer-type sensor **34** is also disposed within the housing **10** and it responds to movement and vibrations reaching it by emitting an electrical signal train on its output line **36**. The accelerometer **34** may be a single axis device, but preferably is capable of sensing accelerations along three axes. The accelerometer output on line **36** is applied to signal processing circuitry shown enclosed by broken line box **38**. While the signal processing circuitry may include additional amplifying and wave shaping components, the heart thereof comprises a plurality of filters **40**, **42**, **44** and **46**. These filters are preferably bandpass filters whose upper and lower cut-off frequencies defining the pass band of each are set to isolate electrical signal components from the accelerometer output signal relating to the patient's physical activity (filter I), respiratory activity (filter II) and heart sounds (filter III).

With no limitation intended, the bandpass filter **40** may have a pass band between about 1 Hz and 10 Hz. This pass band is found to provide an output signal on line **48** relating to the patient's state of activity, such as when at rest or when engaged in exercise.

Bandpass filter **42** may have its pass band set between 0.05 Hz and 1.0 Hz which is sufficient to isolate signal artifacts in the accelerometer output due to inspiration and expiration, with the resulting signal component appearing on output line **50**.

Signal components due to heart beat activity and the flow of blood through the heart can be extracted from the accelerometer output signal on line **36** by providing band pass filter **44** with a pass band that is between about 1 Hz and 140 Hz. Although choosing 1–140 Hz seems like an overlap of activity filter (1–10 Hz) in order to 3rd and 4th heart sounds, frequencies lower than 10 Hz are needed. To pick up 1st and 2nd heart sounds, especially when the patient is exercising, a 10–140 Hz bandwidth is needed. Signal components related to turbulent flow in partially occluded coronary arteries can be detected in the frequency range of 200–800 Hz.

Referring to FIG. **3**, with the monitor of the present invention implanted in the right pectoral region of the body, it is possible to derive three signal components from the accelerometer output signal. Typical waveforms of the outputs from activity filter **40**, respiration filter **42** and the heart sound filters **44** are shown at the respective outputs thereof. However, high frequency heart sound due to turbulent is not shown.

A bus **51** connects the microprocessor-based controller **26** to the filter modules **40**, **42**, **44** and **46** allowing the filter constants to be programmed and also providing a multiplexing function whereby any one of the filter channels can be selected to apply its output to the input of the A/D module **30**. Control signals on the bus **48** applied to the A/D module may also be used to program its sampling rate.

The monitor **10**, in its ability to track and store patient activity and respiration signals measured by means of the accelerometer sensor **34**, can be used to track patient's quality of life as well as to optimize drug or pacing therapy in patients suffering from congestive heart failure. The activity profile can also be quantified to objectively gather data for prognosis of patients with certain modes of therapy. As mentioned in the aforereferenced Walsh et al. publication, weekly measured pedometer scores have been shown to be stronger predictors of mortality compared to any parameter derived from symptom-limited exercise tests. From assessing respiratory signals, it has been shown that mortality is higher in patients with heart failure who develop Cheyne-Stokes respiration during sleep than CHF patients without Cheyne-Stokes. (See Hanly PJ, Zuberi-Khokhar NS "Increased Mortality Associated with Cheyne-Stokes Respiration in Patients With Congestive Heart Failure", *Am. J. Respir Crit Care Med,* 1996 Jan; 153(1):272–276.) The heart sound signals derived from the accelerometer can be processed to yield pulse pressure and other useful information. The third and fourth heart sounds have been determined to be related to ventricular filling, with the third heart sound corresponding to the rapid filling phase and the fourth heart sound to atrial systole. Studies have shown that the third heart sound occurs immediately after the E wave and is related to the sudden deceleration of the blood flow during passive filling of the ventricle. (See Manson AL et al., "Relationship of the Third Heart Sound to Transmitral Flow Velocity Deceleration", *Circulation* 1995 Aug 1;92(3) :388–394.) It has been shown that the onset of a third heart sound during the course of evolving heart failure is coincident with the development of increased left ventricular chamber stiffness and the manifestation of rapid deceleration of early mitral inflow velocity. (See Kono T et al., "Hemodynamic Correlates of the Third Heart Sound During the Evolution of Chronic Heart Failure" *J Am Coll Cardiol* 1993 Feb 21(2):419–423.) The presence of a third heart sound has also been shown to be highly predictive of an abnormal ejection fraction, higher left ventricular filling pressure, larger left atrium and more severe mitral regurgitation. (See Patel R. et al, "Implications of an Audible Third Heart Sound in Evaluating Cardiac Function", *West J Med* 1993 Jun;158 (6):606–609 and Pinamonti B et al, "Restrictive Left Ventricular Filling Pattern in Dilated Cardiomyopathy Assessed by Doppler Echocardiography: Clinical, Echocardiographic and Hemodynamic Correlations and Prognostic Implications. Heart Muscle Disease Study Group" *J Am Coll Cardiol* 1993 Sep 22(3):808–815.) Studies have revealed that fourth heart sound occurred at the onset of atrial flow and consistently before the timing of peak atrial inflow velocity. (See Vancheri F, Gibson D, "Relation of Third and Fourth Heart Sounds to Blood Velocity During Left Ventricular Filling", *Br Heart J* 1989 Feb;61(2):144–148.) A clearly audible fourth heart sound detected one month after the onset of myocardial infarction increases the risk of adverse cardiac events. (See Ishikawa M. et al, "Prognostic Significance of a Clearly Audible Fourth Heart Sound Detected a Month After an Acute Myocardial Infarction" *Am J Cardiol* 1997 Sep 1; 80(5):619–621.)

The time from onset of electrical activity to the start of ejection, namely, pre-ejection period can be derived from

first heart sound. Systemic arterial pulse pressure can also be derived based on first and second heart sounds. The time to second heart sound can also be used as a rate governor to avoid higher pacing rate that can compromise the patient hemodynamically.

This invention has been described herein in considerable detail in order to comply with the patent statutes and to provide those skilled in the art with the information needed to apply the novel principles and to construct and use such specialized components as are required. However, it is to be understood that the invention can be carried out by specifically different equipment and devices, and that various modifications, both as to the equipment and operating procedures, can be accomplished without departing from the scope of the invention itself.

What is claimed is:

1. A monitor for obtaining and storing physiologic information comprising:

(a) a moisture impervious, biocompatible housing having a plurality of electrodes on an exterior surface thereof contacting dermal tissue of a patient in whom the monitor is implanted for detecting ECG signals;

(b) an accelerometer contained within said housing for detecting mechanical vibration of the housing due to physical activity of the patient and due to heart sounds, and respiratory activity and turbulent blood flow in partially occluded coronary arteries and producing an electrical signal proportional to such activity;

(c) signal processing means coupled to receive said electrical signal for isolating components of said electrical signal due to physical activity, respiratory activity, heart sounds and turbulent blood flow in partially occluded coronary arteries;

(d) means for converting said ECG signals and said signal components to digital data;

(e) means coupled to the converting means for storing said digital data in a memory at addressable locations; and

(f) means responsive to a signal applied externally of the patient's body adapted to telemeter the stored digital data to an external device.

2. The monitor as in claim 1 wherein the signal processing means includes bandpass filters tuned to isolate said signal components due to physical activity, respiration and heart sound from one another.

3. The monitor as in claim 2 wherein the bandpass filter for isolating a component of physical activity has a pass band between about 1 Hz and 10 Hz.

4. The monitor as in claim 2 wherein the bandpass filter for isolating components due to respiration has a pass band between about 0.05 Hz and 1 Hz.

5. The monitor as in claim 2 wherein the bandpass filter for isolating the component due to heart sounds has a pass band between about 1 Hz and 140 Hz.

6. The monitor as in claim 2 wherein the bandpass filter for isolating the components due to turbulent blood flow in partially occluded coronary arteries has a pass-band between about 200 Hz and 800 Hz.

7. The monitor as in claim 1 wherein upper and lower cut-off frequencies defining a pass band for the bandpass filter are programmable.

8. The monitor as in claim 1 and further including multiplexer means operatively coupled to selectively apply said signal components to the converting means.

9. The monitor as in claim 1 wherein the means coupled to the converting means for storing the digital data includes a programmed microprocessor.

10. The monitor as in claim 9 wherein the microprocessor is programmed to initiate data storage at the onset of a predetermined event detected in the ECG signal.

11. The monitor as in claim 9 wherein the microprocessor is programmed to initiate data storage at the onset of a predetermined event detected in any one of the isolated components.

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